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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,242	12/21/2001	Stephanie K. Hall	PC11026AJAK	6652

7590 10/24/2003

Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/032,242	Hall
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Aug 22, 2003* .

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-16* is/are pending in the application.

4a) Of the above, claim(s) *12-16* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *1-11* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *0903*
4) [ ] Interview Summary (PTO-413) Paper No(s). _____ .
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [X] Other: *Detailed Action*

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I and rheumatoid arthritis in Paper No. 0903 is acknowledged. The traversal is on the ground(s) that there is no burden to examine the claims of Group II and other species with Group I claims. This is not found persuasive because as the restriction makes clear, additional search of Group II would require review not only of the 3326 patents in class 435, subclass 91.2 for Group I, but also the 2008 patents in class 536, subclass 22.1 for Group II. Review of these additional searches is prima facie evidence of burden which is not rebutted.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure (page 11, lines 21-22) is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicant discloses "cysteine nucleotide"(Page 24, last line to page 25, first line) at positions -31 and +3953 in an IL-beta gene haplotype. This disclosure is objected to as there is no such nucleotide known as "cysteine nucleotide" to an ordinary practitioner and in any prior art in the field of molecular biology. Applicant is required to make necessary change.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for detecting psoriases in Caucasian human subjects involving "cysteine nucleotide "(?) (Page 24, last line to page 25, first line) does not reasonably provide enablement for detecting any inflammatory disorder in any mammal by detecting "cytosine nucleotides" at positions -31 and +3953 in an IL-beta gene haplotype. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Court in re Wands, 8 USPQ2d 1400 (CA FC 1988) stated with regard to enablement that

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the

presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

Here, the claim is broadly drawn to detecting validity of any interferon therapy for any individual. However, the specification does not provide guidance commensurate in scope with this claim, teaching only two interferon alpha and beta resulting in induced hybridization reaction. The specification provides minimal guidance regarding methods for the identification of alternate inflammatory disorder other than psoriasis. There is only one working example (Example II) of detecting psoriases in Caucasian human subjects involving "cysteine nucleotide "(?), whereas claim is directed to haplotype detection comprising "cytosine nucleotides". It is highly unpredictable whether or what other inflammatory diseases would be detected in the context of other huge number of inflammatory diseases database and numerous mammalian species on the face of the earth. It is therefore highly unpredictable whether other detection strategies can be identified which meets this specific criteria regarding any inflammatory disorder in any mammal. Further, identification of additional detection process will be by the trial and error method. This trial and error requirement is borne out because effects of IL-1 beta gene haplotype on any inflammatory disorder in any mammal cannot be readily deduced, even where the genetic as well as metabolic pathways are known. Further, each haplotype has unpredictable effects on metabolic function and inflammatory disorders, and no general method for a priori selection of disease detection is presented. It would require a large amount of experimentation, potentially including

the detection of hundreds of inflammatory disorders in thousands of mammalian species in order to identify additional detection methods with the claimed functionality. Given the Wand's factors opposing the full scope of enablement including the limited teaching in the specification, the presence of only one insufficient and contradictory working example ("cysteine nucleotide"(Page 24, last line to page 25, first line) at positions -31 and +3953 in an IL-beta gene haplotype disclosed, whereas "cytosine nucleotide" is claimed) the teaching of unpredictability in the prior art, the unpredictability of the art, the breadth of the claim, and the large amount of experimentation needed, with only the skill level in the art being neutral towards enablement, it is concluded that undue experimentation is necessary to make and use the invention as broadly claimed.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746 4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti,

Patent Examiner,

October 2, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600